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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,768	06/19/2001	Mark A. Exley	01948/074002	4022
21559	7590	09/28/2005		EXAMINER
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110				JALLA, SANJOO
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/885,768	EXLEY ET AL.	
	Examiner	Art Unit	
	Sanjoo Shree Jalla	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 June 2001.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-5 and 7 drawn to a purified antibody, a hybridoma that produces an antibody and a combination of purified antibodies that preferentially binds a CDR3-loop of T cell antigen receptor (TCR), classified in Class 530, subclass 387.1.

II. Claims 1-5 and 7 drawn to a purified antibody, a hybridoma that produces an antibody and a combination of purified antibodies that preferentially binds an α - β junction of TCR, classified in Class 530, subclass 387.1.

III. Claims 1-5 and 7 drawn to a purified antibody, a hybridoma that produces an antibody and a combination of purified antibodies that preferentially binds or modulates the expansion or activation of either NK T cells, CD1d-reactive T cells and $\text{J}\alpha\text{Q}^+$ T cells, classified in Class 530, subclass 387.1.

IV. Claim 6 drawn to a bifunctional antibody that preferentially binds a CDR3-loop of TCR, classified in Class 530, subclass 387.3.

V. Claim 6 drawn to a bifunctional antibody that preferentially binds an α - β junction of TCR, classified in Class 530, subclass 387.3.

VI. Claim 6 drawn to a bifunctional antibody that preferentially binds or modulates the expansion or activation of either NK T cells, CD1d-reactive T cells and J α Q+ T cells, classified in Class 530, subclass 387.3.

VII. Claim 8, drawn to a purified T cell subpopulation, wherein said T cells are specifically bound by an antibody or a combination of antibodies, wherein said antibody or said antibody combination preferentially binds a CDR3-loop of TCR, classified in Class 435, subclass 7.1.

VIII. Claim 8, drawn to a purified T cell subpopulation, wherein said T cells are specifically bound by an antibody or a combination of antibodies, wherein said antibody or said antibody combination preferentially binds an α - β junction of TCR, classified in Class 435, subclass 7.1.

IX. Claim 8, drawn to a purified T cell subpopulation, wherein said T cells are specifically bound by an antibody or a combination of antibodies, wherein said antibody or said antibody combination preferentially binds or modulates the expansion or activation of either NK T cells, CD1d-reactive T cells and J α Q+ T cells, classified in Class 435, subclass 7.1.

X. Claims 9 and 11, drawn to a method of generating an antibody, that preferentially binds a CDR3-loop of TCR comprising immunizing a mammal with coupled peptides, classified in Class 424, subclass 184.1.

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XI. Claims 9 and 11, drawn to a method of generating an antibody, that preferentially binds an α - β junction of TCR comprising immunizing a mammal with coupled peptides, classified in Class 530, subclass 388.75.

XII. Claims 9 and 11, drawn to a method of generating an antibody, that preferentially binds or modulates the expansion or activation of either NK T cells, CD1d-reactive T cells and J α Q+ T cells comprising immunizing a mammal with coupled peptides, classified in Class 530, subclass 388.75.

XIII. Claims 10 and 11, drawn to a method of generating and isolating an antibody that preferentially binds a CDR3-loop of TCR; said method comprising immunizing a CD1 or invariant T cell deficient mammal with invariant T cells, classified in Class 530, subclass 388.75.

XIV. Claims 10 and 11, drawn to a method of generating and isolating an antibody that preferentially binds an α - β junction of TCR; said method comprising immunizing a CD1 or invariant T cell deficient mammal with invariant T cells, classified in Class 424, subclass 412.

XV. Claims 10 and 11, drawn to a method of generating and isolating an antibody that preferentially binds or modulates the expansion or activation of either NK T cells, CD1d-reactive T cells and J α Q+ T cells; said method comprising immunizing a CD1 or invariant T cell deficient mammal with invariant T cells, classified in Class 424, subclass 412.

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XVI. Claim 12, drawn to a method of measuring the amount of NK TCRs or the amount of NK T cells in a sample, said method comprising contacting said sample with an antibody that preferentially binds a CDR3-loop of TCR, classified in Class 435, subclass 7.24.

XVII. Claim 12, drawn to a method of measuring the amount of NK TCRs or the amount of NK T cells in a sample, said method comprising contacting said sample with an antibody that preferentially binds an α - β junction of TCR, classified in Class 435, subclass 7.24.

XVIII. Claim 12, drawn to a method of measuring the amount of NK TCRs or the amount of NK T cells in a sample, said method comprising contacting said sample with an antibody that preferentially binds an antibody binding site, classified in Class 435, subclass 7.24.

XIX. Claim 13, drawn to a method of measuring the amount of CD1d-reactive TCRs or the amount of CD1d-reactive T cells in a sample, said method comprising contacting said sample with an antibody that preferentially binds a CDR3-loop of TCR, classified in Class 424, subclass 154.1.

XX. Claim 13, drawn to a method of measuring the amount of CD1d-reactive TCRs or the amount of CD1d-reactive T cells in a sample, said method comprising contacting said sample with an antibody that preferentially binds an α - β junction of TCR, classified in Class 424, subclass 154.1.

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XXI. Claim 13, drawn to a method of measuring the amount of CD1d-reactive TCRs or the amount of CD1d-reactive T cells in a sample, said method comprising contacting said sample with an antibody that preferentially binds an antibody binding site, classified in Class 424, subclass 154.1.

XXII. Claim 14, drawn to a method of measuring the amount of J α Q+TCRs or the amount of J α Q+ T cells in a sample, said method comprising contacting said sample with an antibody or a combination of antibodies that preferentially binds a CDR3-loop of TCR, classified in Class 424, subclass 154.1.

XXIII. Claim 14, drawn to a method of measuring the amount of J α Q+TCRs or the amount of J α Q+ T cells in a sample, said method comprising contacting said sample with an antibody or a combination of antibodies that preferentially binds an α - β junction of TCR, classified in Class 424, subclass 154.1.

XXIV. Claim 14, drawn to a method of measuring the amount of J α Q+TCRs or the amount of J α Q+ T cells in a sample, said method comprising contacting said sample with an antibody or a combination of antibodies that preferentially binds an antigen binding site, classified in Class 424, subclass 154.1.

XXV. Claim 15, drawn to a method of visualizing the amount of NK TCRs or the amount of NK T cells in a sample, said method comprising contacting said sample with an antibody that preferentially binds a CDR3-loop of TCR, classified in Class 435, subclass 9.3.

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XXVI. Claim 15, drawn to a method of visualizing the amount of NK TCRs or the amount of NK T cells in a sample, said method comprising contacting said sample with an antibody that preferentially binds an α - β junction of TCR, classified in Class 435, subclass 9.3.

XXVII. Claim 15, drawn to a method of visualizing the amount of NK TCRs or the amount of NK T cells in a sample, said method comprising contacting said sample with an antibody that preferentially binds an antibody binding site, classified in Class 435, subclass 9.3.

XXVIII. Claim 16, drawn to a method of visualizing the amount of CD1d-reactive TCRs or the amount of CD1d-reactive T cells in a sample, said method comprising contacting said sample with an antibody that preferentially binds a CDR3-loop of TCR, classified in Class 424, subclass 85.1.

XXIX. Claim 16, drawn to a method of visualizing the amount of CD1d-reactive TCRs or the amount of CD1d-reactive T cells in a sample, said method comprising contacting said sample with an antibody that preferentially binds an α - β junction of TCR, classified in Class 424, subclass 85.1.

XXX. Claim 16, drawn to a method of visualizing the amount of CD1d-reactive TCRs or the amount of CD1d-reactive T cells in a sample, said method comprising contacting said sample with an antibody that preferentially binds an antibody binding site, classified in Class 424, subclass 85.1.

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XXXI. Claim 17, drawn to a method of visualizing the amount of J α Q+TCRs or the amount of J α Q+ T cells in a sample, said method comprising contacting said sample with an antibody or a combination of antibodies that preferentially binds a CDR3-loop of TCR, classified in Class 424, subclass 85.1.

XXXII. Claim 17, drawn to a method of visualizing the amount of J α Q+TCRs or the amount of J α Q+ T cells in a sample, said method comprising contacting said sample with an antibody or a combination of antibodies that preferentially binds an α - β junction of TCR, classified in Class 424, subclass 85.1.

XXXIII. Claim 17, drawn to a method of visualizing the amount of J α Q+TCRs or the amount of J α Q+ T cells in a sample, said method comprising contacting said sample with an antibody or a combination of antibodies that preferentially binds an antigen binding site, classified in Class 424, subclass 85.1.

XXXIV. Claims 18 and 19, drawn to a method of diagnosing a subject with a condition or an increased risk for a condition; said method comprising contacting a sample from said subject with an antibody or a combination of antibodies that preferentially binds a CDR3-loop of TCR, classified in Class 435, subclass 7.23.

XXXV. Claims 18 and 19, drawn to a method of diagnosing a subject with a condition or an increased risk for a condition; said method comprising contacting a sample from said subject with an antibody or a combination of antibodies that

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preferentially binds an α - β junction of TCR, classified in Class 435, subclass 7.23.

XXXVI. Claims 18 and 19, drawn to a method of diagnosing a subject with a condition or an increased risk for a condition; said method comprising contacting a sample from said subject with an antibody or a combination of antibodies that preferentially binds an antigen binding site, classified in Class 435, subclass 7.23.

XXXVII. Claims 20, drawn to a method of treating or preventing a disease in a mammal; said method comprising administering to said mammal an antibody or combination of antibodies that preferentially binds a CDR3-loop of TCR, classified in Class 424, subclass 176.1.

XXXVIII. Claims 20, drawn to a method of treating or preventing a disease; said method comprising administering to said mammal an antibody or combination of antibodies that preferentially binds an α - β junction of TCR classified in Class 424, subclass 176.1.

XXXIX. Claims 20, drawn to a method of treating or preventing a disease; said method comprising administering to said mammal an antibody or combination of antibodies that preferentially binds an antigen binding site, classified in Class 424, subclass 176.1.

XL. Claims 21 and 22, drawn to a method of inhibiting T cell pathogenesis in a mammal using an antibody that is linked to a

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toxin or a radiolabel; said method comprising administering to said mammal an antibody or combination of antibodies that preferentially binds a CDR3-loop of TCR, classified in Class 424, subclass 177.1.

XLI. Claims 21 and 22, drawn to a method of inhibiting T cell pathogenesis in a mammal using an antibody that is linked to a toxin or a radiolabel; said method comprising administering to said mammal an antibody or combination of antibodies that preferentially binds an α - β junction of TCR, classified in Class 424, subclass 177.1.

XLII. Claims 21 and 22, drawn to a method of inhibiting T cell pathogenesis in a mammal using an antibody that is linked to a toxin or a radiolabel; said method comprising administering to said mammal an antibody or combination of antibodies that preferentially binds an antigen binding site, classified in Class 424, subclass 177.1.

XLIII. Claims 23-30, drawn to a method of increasing the size of a subpopulation of T cells; said method comprising contacting a sample comprising said T cells with an antibody or a combination of antibodies that preferentially binds a CDR3-loop of TCR in presence or absence of alpha-galactosylceramide antigen, classified in Class 424, subclass 178.1.

XLIV. Claims 23-30, drawn to a method of increasing the size of a subpopulation of T cells; said method comprising contacting a sample comprising said T cells with an antibody or a combination of antibodies that preferentially binds an α - β junction of TCR,

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in presence or absence of alpha-galactosylceramide antigen, classified in Class 424, subclass 178.1.

XLV. Claims 23-30, drawn to a method of increasing the size of a subpopulation of T cells; said method comprising contacting a sample comprising said T cells with an antibody or a combination of antibodies that preferentially binds an antigen binding site, in presence or absence of alpha-galactosylceramide antigen, classified in Class 424, subclass 178.1.

XLVI. Claims 31 and 32, drawn to a method of increasing the size of a subpopulation of T cells; said method comprising contacting said T cells with an antibody or a combination of antibodies that preferentially binds a CDR3-loop of TCR; said contacting conducted under conditions that allow said contacting to increase the number of said T cells, classified in Class 424, subclass 178.1.

XLVII. Claims 31 and 32, drawn to a method of increasing the size of a subpopulation of T cells; said method comprising contacting said T cells with an antibody or a combination of antibodies that preferentially binds an α - β junction of TCR, said contacting conducted under conditions that allow said contacting to increase the number of said T cells, classified in Class 424, subclass 178.1.

XLVIII. Claims 31 and 32, drawn to a method of increasing the size of a subpopulation of T cells; said method comprising contacting said T cells with an antibody or a combination of antibodies that preferentially binds an antigen binding site,

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said contacting conducted under conditions that allow said contacting to increase the number of said T cells, classified in Class 424, subclass 178.1.

XLIX. Claims 33-38, drawn to a method of increasing the size of a subpopulation of T cells; said method comprising contacting said T cells with an antibody or a combination of antibodies that preferentially binds a CDR3-loop of TCR; said contacting conducted under conditions that allow complex formation between said T cells and said body in the presence or absence of alpha-galactosylceramide antigen, classified in Class 424, subclass 178.1.

L. Claims 33-38, drawn to a method of increasing the size of a subpopulation of T cells; said method comprising contacting said T cells with an antibody or a combination of antibodies that preferentially binds an α - β junction of TCR; said contacting conducted under conditions that allow complex formation between said T cells and said body, in the presence or absence of alpha-galactosylceramide antigen, classified in Class 424, subclass 178.1.

LI. Claims 33-38, drawn to a method of increasing the size of a subpopulation of T cells; said method comprising contacting said T cells with an antibody or a combination of antibodies that preferentially binds a antigen binding site antigen receptor (TCR); said contacting conducted under conditions that allow complex formation between said T cells and said body, in the presence or absence of alpha-galactosylceramide antigen, classified in Class 424, subclass 178.1.

LII. Claims 39-42, drawn to a method of purifying a subpopulation of T cells using antibody that is covalently linked to a fluorescent label or to a magnetic label; said method comprising contacting said sample with an antibody or a combination of antibodies that preferentially binds a CDR3-loop of TCR, classified in Class 530, subclass 388.7.

LIII. Claims 39-42, drawn to a method of purifying a subpopulation of T cells using antibody that is covalently linked to a fluorescent label or to a magnetic label; said method comprising contacting said sample with an antibody or a combination of antibodies that preferentially binds an α - β junction of TCR, Classified in Class 530, subclass 388.7.

LIV. Claims 39-42, drawn to a method of purifying a subpopulation of T cells using antibody that is covalently linked to a fluorescent label or to a magnetic label; said method comprising contacting said sample with an antibody or a combination of antibodies that preferentially binds a antigen binding site antigen receptor (TCR), classified in Class 530, subclass 388.7.

2. Groups I-IX are unrelated products. An antibody, a bifunctional antibody and a purified T cell subpopulation, differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

3. Groups (I-IX) and (X-LIV) are related as products and processes of use. The inventions can be shown to be distinct if

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either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, bifunctional antibodies of groups 4-6, may be used for binding different immunogens or for delivery system and purified T cells of groups 7-9, may be used for proliferations assays or even for production of cytokines.

4. Groups I-III and X-XV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, antibody can be made using phage display libraries.

5. Groups XVI-LIV are different methods. In the instant case the different inventions are drawn to methods comprising different method steps, different reagents, resulting in different end points. For example, the steps used in the method of visualizing the T-cells of group XXV-XXXIII are distinct from the steps required for the method of measuring different T-cells in groups (XVI-XXIV). Furthermore, the steps and endpoints are different in the method of groups XXXIV-XXXVI, where a condition is diagnosed in a subject, vs. the method of groups XL- XLII, where T cell pathogenesis in a mammal is inhibited. The reagents, method steps and endpoints are also different in a

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method of increasing size of subpopulation of T-cells of groups XLIII-LI, which involves contacting T cells with an antibody or a combination of antibodies in presence or absence of alpha-galactosylceramide antigen, and a method of purifying a subpopulation of T cells of groups LII-LIV which involves using an antibody or a combination of antibodies under conditions that allow complex formation followed by isolating T-cells from the complex.

Species Election

If applicant elects a method of groups XXXIV-XXXIX and groups XLIX-LI, he is required to pick a specific disease such as recited in claims 18, 20, and 38. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints, thus each condition represents patentably distinct subject matter. For example, graft versus host disease (GVHD) is different than cancer because GVHD is a major complication of bone marrow transplant where individual's donor lymphocytes respond to antigenic differences of the recipient whereas in cancer, body's cells become abnormal and divide without control. Similarly, viral infection is different from bacterial infection as the pathogen causing viral infection is a virus whereas pathogen causing bacterial infection is a bacteria.

6. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the

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claims shall be restricted if no generic claim is finally held to be allowable.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection is governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

9. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all

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criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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12. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art because of their recognized divergent subject matter. Further, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Sanjoo S Jalla whose telephone number is 571-272-4453. The examiner can normally be reached Monday through Friday from 8:30-5pm.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on

access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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9/19/08
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